UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLIE UTTS and CIARA UTTS,	:	
Plaintiffs,	:	Civil Action No. 1:16-cv-05668-DLC
-against-	:	
BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	:	ORAL ARGUMENT REQUESTED
Defendants.	:	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY AND PFIZER INC.'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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Defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer") (collectively, "Defendants") hereby submit this Memorandum in Support of their Motion to Dismiss Plaintiffs' Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). For the reasons discussed below, Plaintiffs' Amended Complaint should be dismissed in its entirety.

PRELIMINARY STATEMENT

On July 15, 2016, Plaintiffs filed their original complaint in this action, alleging that Mr. Utts experienced internal bleeding and other injuries as a result of taking Defendants' anticoagulant medication Eliquis (apixaban). Plaintiffs primarily alleged that Defendants failed to warn about the bleeding risk with Eliquis and about the lack of an agent to reverse its anticoagulant effect. Those allegations stood in stark contrast to the Eliquis labeling, which always has warned prominently about the bleeding risk associated with Eliquis use—the word "bleeding" appears no less than 65 times in the label—and that no method exists to reverse the anticoagulant effect of the medication. Defendants moved to dismiss Plaintiffs' complaint in its entirety, on federal preemption, adequacy of the warnings, and other grounds.

On December 23, 2016, the Court issued an Order granting Defendants' motion. The Court held that Plaintiffs' design defect claims were preempted by federal law, and it dismissed those claims with prejudice. The Court also dismissed Plaintiffs' warnings claims on federal preemption grounds, finding that Plaintiffs had not alleged that any "newly acquired information" existed that would have permitted Defendants to independently make changes to the warnings in the FDA-approved Eliquis labeling. The Court gave Plaintiffs an opportunity to amend their pleadings to address this deficiency, as well as to address pleading deficiencies in their manufacturing defect, warranty, fraud, and consumer protection causes of action, all of which the Court dismissed with leave to amend. The Court did not reach Defendants' adequacy of the warnings argument, reserving that until after the preemption issue is resolved.

On January 20, 2017, Plaintiffs filed their Amended Complaint. The Amended Complaint includes a host of new allegations. It does not, however, cure the fundamental deficiencies that underlie Plaintiffs' claims, particularly when viewed in the context of a label that always has warned prominently and clearly of the risk of the very injury alleged by Plaintiffs.

Plaintiffs' Claims Are Preempted. First, Plaintiffs still have not alleged that any "newly acquired information" exists that would have allowed Defendants to independently make any relevant changes to the Eliquis labeling. To be sure, Plaintiffs point to three pieces of post-approval data in their Amended Complaint. But none of those includes any information about the nature, severity, or frequency of the bleeding risk (or any other relevant risk) associated with Eliquis use that is new or different from the very explicit and detailed information already included in the FDA-approved labeling. *See* 21 C.F.R. § 314.3(b). Moreover, each of the pieces of data cited by Plaintiffs *post-dates Mr. Utts's alleged injury by more than a year*, and involves potential risks that have no relationship to Plaintiffs' litigation claims. Accordingly, the post-approval data referenced in the Amended Complaint could not have formed the basis for a relevant labeling change pursuant to the Changes Being Effected ("CBE") regulations at the time Mr. Utts took Eliquis. For this reason, Plaintiffs' warnings claims, which underlie all of their causes of action, should be dismissed on federal preemption grounds. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015); *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

The Eliquis Label Is Adequate As a Matter of Law. Second, although Plaintiffs include a laundry list of new warnings claims and additional details regarding the alleged labeling deficiencies, a careful review of those claims only further supports Defendants' argument that the Eliquis label—which prominently warns of the risk of the very injury alleged by Plaintiff—is adequate as a matter of law. Indeed, each of the alleged deficiencies outlined in detail in the

Amended Complaint is contradicted by the plain text of the original, FDA-approved Eliquis label. For that reason also, Plaintiffs' warnings claims should be dismissed. *See Dash v. Roche Labs.*, 74 F.3d 1245 (9th Cir. 1996).

Plaintiffs' Individual Causes of Action Are Inadequately Pled. Third, Plaintiffs still have not corrected the pleading deficiencies that led this Court to dismiss their manufacturing defect, breach of express and implied warranty, fraud / negligent misrepresentation, and consumer protection claims. Virtually all of these claims are based on threadbare allegations that are devoid of sufficient factual support to create a plausible cause of action. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To the extent that Plaintiffs have attempted to add more specific allegations (for example, with regards to their fraud claims), those allegations are preempted by federal law and/or contradicted by the FDA-approved labeling. Accordingly, each of those causes of action should be dismissed.

For these reasons, and as discussed below, Plaintiffs' Amended Complaint should be dismissed in its entirety and with prejudice.

LEGAL STANDARD FOR A MOTION TO DISMISS

In evaluating a motion to dismiss, federal courts follow the pleading requirements established by the U.S. Supreme Court in *Ashcroft v. Iqbal*, 556 U.S. 662, and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). "To survive a [Rule 12(b)(6)] motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). Additionally, "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Twombly*, 550 U.S. at 555. This "plausibility standard" requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. "[A] plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and

conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Twombly*, 550 U.S. at 555 (internal quotation marks and citations omitted). Although a plaintiff's allegations generally must be accepted as true, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Brown v. Daikin Am. Inc.*, 756 F.3d 219, 225 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555). Furthermore, the court need not accept as true "any allegations that are contradicted by documents deemed to be part of the complaint, or materials amenable to judicial notice." *In re Yukos Oil Co. Sec. Litig.*, No. 04 Civ. 5243, 2006 WL 3026024, at *12 (S.D.N.Y. Oct. 25, 2006).

ARGUMENT

I. Plaintiffs' Warning Claims Are Preempted by Federal Law.

As this Court explained in its December 23, 2016 Order, "federal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the CBE [Changes Being Effected] regulation." Order, at 30-31. A manufacturer is permitted to use the CBE process to make "moderate changes" to its label unilaterally (*i.e.*, without prior FDA approval) only if the changes "reflect newly acquired information."[1] 21 C.F.R. § 314.70(c)(6)(iii). Such "newly acquired information" is defined as "data, analyses, or other information *not previously submitted to the Agency*, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (*e.g.*, meta-analyses) *if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA*." 21 C.F.R. § 314.3(b) (emphasis added). Absent plausible allegations that the manufacturer had such "newly acquired information," it is appropriate to dismiss failure-to-

[1] A manufacturer cannot make unilateral major changes to the labeling pursuant to the CBE regulation. *See* 21 C.F.R. § 314.70(b). Changes to a boxed warning and to the Medication Guide are considered to be "major changes". *See* 21 C.F.R. § 314.70(b)(2)(v).

warn claims as preempted. Order, at 18, n.6.

In ruling on Defendants' original motion to dismiss, this Court found that Plaintiffs' "complaint d[id] not allege that the defendants were in possession of 'newly acquired information' such that they could, pursuant to the CBE regulation, act independently of the FDA to update the Eliquis label with any of the fourteen categories of additional or improved warnings listed in the complaint." *Id*. at 31. For that reason, the Court held that Plaintiffs' warnings claims, whether based on a theory of negligence or strict liability, were preempted and dismissed those claims, with leave to amend. *See id*. at 31-32. This holding is entirely consistent with Supreme Court precedent in *Wyeth v. Levine*, 555 U.S. 555 and *PLIVA, Inc. v. Mensing*, 564 U.S. 604 and with the First Circuit's holding in *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34.

In response, Plaintiffs filed an amended complaint, which includes a laundry list of new failure-to-warn claims and a new section captioned "Post-Approval Data." *See* Am. Compl. ¶¶ 50-60. In that section, Plaintiffs identify three pieces of evidence which they contend constitute "newly acquired information." *See id.* These are: (1) a September 2015 ISMP QuarterWatch report, (2) a 2016 BMJ article, and (3) a 2016 FDA FAERS Signal Report. *See id.* As discussed below, this "Post-Approval Data" is not "newly acquired information" as defined in the CBE regulation and does not provide a basis upon which Defendants could have independently made any changes to Eliquis product labeling, particularly during the period relevant to Plaintiffs' claims.

A. The Post-Approval Data Cited By Plaintiffs Post-Dates Mr. Utts's Injury.

Mr. Utts allegedly "suffered a severe gastrointestinal bleeding event" on or about July 16, 2014. *See* Am. Compl. ¶¶ 14-15. Each of the three pieces of post-approval data cited by Plaintiffs post-dates Mr. Utts's alleged injury by at least a year. The ISMP QuarterWatch Report

was published on September 23, 2015, and includes analyses of adverse event data from the third and fourth quarter of 2014. *See* Ex. 1 (ISMP QuarterWatch), at 1. The BMJ Article was accepted for publication on May 20, 2016, *see* Ex. 2 (Larsen 2016), at 1, and the FDA report is based on adverse event data collected between July and September 2016. *See* Ex. 3 (FDA Signal Report), at 1. Accordingly, none of these data could have served as the basis for a CBE label change during the period of time relevant to Plaintiffs' claims (between initial Eliquis approval in December 2012 and Mr. Utts's alleged injury in July 2014).[2] On that basis alone, the Court should dismiss Plaintiffs' Amended Complaint with prejudice.

B. The Post-Approval Data Cited by Plaintiffs Does Not Provide Any New Information About the Nature of the Bleeding Risk with Eliquis.

Although Plaintiffs include a laundry list of warnings claims in their Complaint, the essence of all the claims is that Defendants failed to adequately warn about the bleeding risk with Eliquis. Thus, to provide the basis for a CBE label change relevant to their claims, any post-approval data would have to include new information about the nature and/or severity of the bleeding risk associated with Eliquis use. None does.[3]

ISMP QuarterWatch Report. Plaintiffs first state that the ISMP report "noted that Eliquis, when used in conjunction with typical platelet inhibitors [aspirin, NSAIDs, and SSRIs, among others], show [*sic*] an increased risk of bleeding events compared to the Defendants' prior clinical data (ARISTOTLE)." Am. Compl. ¶ 51. No such statement appears in the report. On the contrary, the report states that Eliquis "showed the strongest safety profile," "accounted for the fewest reports and the fewest patient deaths both before and after adjusting for patient

[2] For the same reason, Plaintiffs' vague allegations regarding the volume of adverse events reported in 2015 for Eliquis, *see* Am. Compl. ¶ 56, bear no relevance to their litigation claims.

[3] Plaintiffs' Complaint includes reference to all three documents, as well as the Eliquis label and FDA's Medical Review. *See* Am. Compl. ¶¶ 34, 40, 51-60. The Court may take notice of the entirety of the documents referenced in the Amended Complaint. *See Becker v. Cephalon, Inc.*, No. 14 Civ. 3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015).

exposure," and "had the best adverse event safety profile by several measures." Ex. 1 (ISMP QuarterWatch), at 2, 12.

Plaintiffs also highlight (in bold) the fact that the ISMP report notes that a trial evaluating the safety and efficacy of Eliquis for use in patients with Acute Coronary Syndrome "was stopped because of excess bleeding and no identifiable benefits." Am. Compl. ¶ 53. The significance of this is unclear given that Mr. Utts does not allege that he was being treated with Eliquis for "acute coronary syndrome," but rather for atrial fibrillation.[4] *See id*. ¶ 14. Moreover, the results of the trial referenced by Plaintiffs (APPRAISE-2) were reviewed by FDA and discussed in the original FDA-approved Eliquis label: "APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo." Ex. 4 (2012 Label), at 10. As such, the trial does not provide any new information that could support a change to the Eliquis label pursuant to the CBE regulation.[5]

Plaintiffs also point to a single sentence from the ISMP report which states that "In the adverse event data, we found *that concomitant therapy with platelet inhibitors while taking anticoagulants* increased the odds of a hemorrhage event by threefold (OR 3.01 $p < 0.01$)," which Plaintiffs claim "is higher than what is indicated in the Eliquis label (See Eliquis Label, Sec. 7.3: Drug Interaction)." Am. Compl. ¶¶ 51-52 (emphasis added). To the extent Plaintiffs contend that this single sentence could be the basis for a relevant labeling change pursuant to the CBE regulation, such claim also fails for numerous reasons.

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[4] Acute coronary syndrome is a term used to describe a range of conditions associated with sudden, reduced blood flow to the heart.

[5] Eliquis is not approved for use in the treatment of acute coronary syndrome, and, thus, no basis exists for Defendants to include specific warnings about potential risks for this indication.

First, the original FDA-approved Eliquis label already prominently warns about the increased bleeding risk when Eliquis is taken in combination with antiplatelet agents. Section 7.3 of the label is titled "Anticoagulants and Antiplatelet Agents" and specifically states that "Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding." Ex. 4 (2012 Label), at 10. The very next sentence reports the results from the APPRAISE-2 clinical trial, in which subjects were treated with Eliquis in combination with antiplatelet agents. *See id.* In that trial, the incidence of major bleeding was 2.77% per year in patients treated with Eliquis plus an antiplatelet agent compared with 0.62% per year in patients treated with placebo (a sugar pill) plus an antiplatelet agent. *See id.* That translates to approximately a 4-fold higher incidence rate in patients receiving combination therapy, a ratio *greater than that quoted in the ISMP report*. Accordingly, the ISMP analysis cited by Plaintiffs does not provide evidence that the bleeding risk with Eliquis is of "a different type or greater severity or frequency" than previously included in submissions to FDA and reported in the Eliquis label, as required under the CBE regulation. 21 C.F.R. § 314.3(b).

Second, the risk estimate cited by Plaintiffs is not specific to Eliquis,[6] but rather is based on combined adverse event data from a number of anticoagulant medications, including warfarin. *See* Ex. 1 (ISMP QuarterWatch), at 12. As such, the incidence rate included in the ISMP report does not provide reliable information about the incidence of bleeding events in patients taking Eliquis in combination with an antiplatelet agent, and it cannot be directly compared to the incidence rates reported in the Eliquis label, which come from randomized, controlled clinical trials specifically evaluating Eliquis.

Third, the risk estimate is based on an analysis of spontaneous adverse event reports, not

[6] Although the authors reported that "[t]he increased risk was found across all three of the novel anticoagulants and warfarin," the authors did not provide any specific risk estimate for Eliquis, and, as discussed above, the authors noted that the event rates for Eliquis were lower than for other anticoagulants. *See* Ex. 1 (ISMP QuarterWatch), at 12.

on data from a controlled clinical trial or observational study. *See id*. It is well-recognized that analysis of spontaneous adverse event data have numerous limitations and provide far less reliable data than controlled studies. *See, e.g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (holding that spontaneous adverse event reports offer "one of the least reliable sources to justify opinions about both general and individual causation"). Indeed, FDA has specifically stated that such data "cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population." *See* Ex. 5 (Questions and Answers on FDA's Adverse Event Reporting System), at 2. For this reason also, the ISMP analysis cannot provide reliable information about the incidence of bleeding events in patients taking Eliquis in combination with antiplatelet therapy.

Fourth, Plaintiffs do not allege that Mr. Utts was taking Eliquis in combination with an antiplatelet agent such as aspirin or Plavix. Accordingly, any potential labeling changes based on an analysis of adverse event reports in patients taking combination therapy have no connection to Plaintiffs' litigation claims.

For all these reasons, the ISMP QuarterWatch Report does not provide any new information that could have supported Defendants independently making any relevant changes to the warnings included in the Eliquis label.

BMJ Article. Plaintiffs state that a 2016 observational study published in British Medical Journal by Larsen et al. reported that "NOACs were not significantly different from warfarin" in terms of their efficacy for reducing stroke risk. Am. Compl. ¶ 57. It is true that the Larsen study did not find a significant difference in ischemic stroke risk when patients taking Eliquis were compared with those taking warfarin. *See* Ex. 2 (Larsen 2016), at 6, fig. 2. That finding is entirely consistent with the data reviewed by FDA and reported in the Eliquis label. *See* Ex. 4 (2012 Label), at 20, tbl. 3 (showing no significant difference in ischemic stroke risk between

Eliquis and warfarin in the ARISTOTLE trial). Furthermore, the relative reduction in ischemic stroke risk relates to the efficacy of Eliquis and has no bearing on potential bleeding risk.[7]

Further, Plaintiffs fail to mention the key, relevant findings from the study. Specifically, the authors found that "[t]he risks of death, any bleeding, or major bleeding were significantly lower for apixaban [Eliquis] . . . compared with warfarin" and noted that the "risks for any bleeding or major bleeding" with Eliquis in the study were "consistent with the results of the NOAC phase 3 clinical trial [ARISTOTLE]." *See* Ex. 2 (Larsen 2016), at 1, 8. The authors further concluded that all novel anticoagulants, including Eliquis, "seem to be safe and effective alternatives to warfarin." *Id*. at 1. Given these consistent findings, the article provides no new information that would support any changes to the warnings and information about the bleeding risk associated with Eliquis included in the original FDA-approved labeling.

FDA Signal Report. Plaintiffs also allege that "FDA itself is conducting a study only recently begun in November 2016, involving investigation into the strong adverse event signal connection between Eliquis and vasculitis." Am. Compl. ¶ 59. The citation points to an FDA website which states that FDA has identified a potential signal in its adverse event database ("FAERS") for a number of different medications, including a potential signal for vasculitis in patients taking the novel anticoagulants Eliquis, Pradaxa, Savaysa, and Xarelto. *See* Ex. 3 (FDA Signal Report), at 1. That potential signal was identified based on an analysis of adverse event reports in the period between July and September 2016. *See id*. As an initial matter, the potential signal relates to vasculitis, which is not a condition Mr. Utts alleges he suffered and is not characterized by bleeding.[8] Furthermore, the website states only that the Agency "is evaluating the need for regulatory action"; no further details are provided, and the website does

[7] An ischemic stroke occurs as a result of an obstruction within a blood vessel supplying blood to the brain. It is not a bleeding event.

[8] *See* Ex. 6 (National Institutes of Health, "What is Vasculitis?").

not state that FDA has reached any conclusion as to whether an increased risk of vasculitis exists with Eliquis (or any of the other novel anticoagulants). *Id*.

Thus, at best, the FDA Signal Report is a preliminary inquiry into a condition that is unrelated to Mr. Utts alleged injury. It is not evidence that could provide any basis for Defendants to change the warnings about the bleeding risk with Eliquis.

C. The Post-Approval Data Cited by Plaintiffs Is Not Relevant to Plaintiffs' Warnings Claims.

Plaintiffs only purport to identify "newly acquired information" related to: (1) the risk of bleeding in patients taking combination therapy with an antiplatelet agent, (2) the relative stroke reduction when compared to warfarin, and (3) the risk of vasculitis. Plaintiffs do not identify any new data relevant to the vast majority of labeling changes they seek, including specifically those relating to the availability of a reversal agent or antidote, the ability to assess or measure Eliquis exposure, the "therapeutic range" of Eliquis, the methods for managing bleeding in patients taking Eliquis, the bleeding risk in ageing patients, the need to monitor renal and hepatic function, the appropriate timing of stopping Eliquis before surgical procedures, the risks associated with head trauma, the methods to adjust dosing, etc.[9] *See* Am. Compl. ¶¶ 82, 101. Accordingly, the only warnings claims that plaintiffs have attempted to support are those that relate to the risk of bleeding in patients taking combination therapy with antiplatelet agents (*see* Am. Compl. ¶¶ 82(u), 101(v) only) and the relative ischemic stroke risk reduction compared to

[9] To the extent Plaintiffs suggest that the Defendants should have included a "Boxed" warning (*see id*. ¶¶ 75-77, 82(n), 101(o)) or added information to the Medication Guide (*see id*. ¶¶ 82(q), 101(r)), FDA regulations prohibit making such changes via the CBE process. *See* 21 C.F.R. § 314.70(b)(2)(v); *see also Dopson-Troutt v. Novartis Pharms. Corp.*, 975 F. Supp. 2d 1209, 1219 (M.D. Fla. 2013) (holding that FDA regulations prohibit manufacturers from changing boxed warnings absent FDA approval); *Ray v. Allergan, Inc.*, Civ. A. No. 3:10CV136, 2012 WL 2120018, at *7 (E.D. Va. June 1, 2012) (same). Likewise, any claims suggesting that Eliquis should be withdrawn from the market are preempted under *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013). *See also* Order, at 23-24.

warfarin (*see id.* ¶ 101(y) only).[10] But, as noted above, those claims bear no relationship to Plaintiffs' causes of action, as Plaintiffs do not allege that Mr. Utts was treated with combination therapy or that Eliquis was not effective in reducing his stroke risk. *See Knoppel v. St. Jude Med., Inc.*, No. SACV 13-383, 2013 WL 12116393, at *5 (C.D. Cal. Sept. 24, 2013) (dismissing failure-to-warn claims where plaintiffs had not alleged a "causal connection between Defendant's failed warnings and the alleged injuries").

In sum, the "Post-Approval Data" cited by Plaintiffs in their Amended Complaint does not constitute "newly acquired information" that could have supported Defendants independently making any relevant changes to the warnings included in the Eliquis label. Accordingly, Plaintiffs' warnings claims, which underlie each and every one of their eleven causes of action, are preempted and should at this time be dismissed with prejudice.

II. The Warnings in the Eliquis Label Are Adequate as a Matter of Law.

In its December 23, 2016 Order, the Court deferred ruling on Defendants' argument that the Eliquis label is adequate as a matter of law, reserving that issue until it had an opportunity to make a final determination on preemption. Order, at 32. In the event that the Court declines to dismiss Plaintiffs' claims on preemption grounds, the Court should dismiss all of Plaintiffs' warnings claims because the Eliquis label is adequate as a matter of law. As discussed in detail in the opening brief, the Eliquis label always has warned "in plain and explicit terms" of the very injury alleged by Plaintiffs, *Dash v. Roche Labs.*, 74 F.3d 1245, in particular emphasizing that Eliquis "can cause serious, potentially fatal bleeding" and that "[t]here is no established way to reverse the anticoagulant effect of apixaban." Ex. 4 (2012 Label), at 1, 5.

In their Amended Complaint, Plaintiffs listed additional details about the alleged warnings deficiencies in a section titled "Post-Approval Clinical Concerns Regarding Eliquis and

[10] There are no allegations in Plaintiffs' Amended Complaint related to a failure to warn of a risk of vasculitis.

Its Labeling." *See* Am. Compl. ¶¶ 61-91. Plaintiffs specifically focus on claims related to "stopping bleeding events," "one size fits all dosing," "surgery and lack of warnings or data," and, to a lesser extent, the risk of bleeding with head trauma and the lack of a reversal agent. *Id*. ¶¶ 61, 62-65, 66-69, 70-72, 73-74, 85-89. Based on these claims, Plaintiffs conclude that "it seems that the warning label for Eliquis is inadequate." *Id*. ¶ 75. However, in each case, Plaintiffs' allegations are contradicted by the plain language of the Eliquis label. *See In re Yukos Oil Co. Sec. Litig.*, 2006 WL 3026024, at *12 (holding that a court need not accept as true allegations that are contraindicated by documents that are subject to judicial notice).[11]

"Stopping Bleeding Events." Plaintiffs claim that no information was included in the relevant Eliquis labeling as to which methods may be used (and which may be ineffective) in managing a bleed in a patient taking Eliquis. *See* Am. Compl. ¶ 64. Plaintiffs further allege that the label "makes no mention of hemodialysis at all," and argue that, had information about hemodialysis been included, Mr. Utts would not have received "unnecessary dialysis treatment." *Id*. ¶ 65. Plaintiffs are mistaken.

The original, FDA-approved label includes a detailed discussion of potential methods for managing bleeding in patients taking Eliquis that is prominently located in the Warnings & Precautions section of the label, under the heading Bleeding. The relevant text appears below:

> There is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for about 24 hours after the last dose, i.e., for about two half-lives. A specific antidote for ELIQUIS is not available. Because of high plasma protein binding, apixaban is not expected to be dialyzable [see Clinical Pharmacology (12.3)]. Protamine sulfate and vitamin K would not be expected to affect the anticoagulant activity of apixaban. There is no experience with antifibrinolytic agents (tranexamic acid, aminocaproic acid) in individuals receiving apixaban. There is neither scientific rationale for reversal nor experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving apixaban. Use of procoagulant reversal agents such as prothrombin

[11] Defendants refer the Court to its original motion for additional information and argument as to the adequacy of the warnings in the Eliquis labeling regarding bleeding generally. *See* Ex. 7 (Defendants' Motion to Dismiss), at 11-14.

> complex concentrate, activated prothrombin complex concentrate, or recombinant factor VIIa may be considered but has not been evaluated in clinical studies. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration [see Overdosage (10)].

Ex. 4 (2012 Label), at 5. Thus, the original Eliquis labeling clearly identifies the available scientific evidence relating to potential methods for managing bleeding in patients taking Eliquis (such as prothrombin complex concentrate, activated prothrombin complex concentrate, recombinant Factor VIIa, and activated oral charcoal) and informs physicians about those methods that are unlikely to be helpful (including protamine sulfate, vitamin K, desmopressin, and aprotinin). In addition, the label specifically states that Eliquis is "not expected to be dialyzable," *i.e.*, that hemodialysis is not expected to be an effective strategy to address bleeding in patients on Eliquis.

"One size fits all" Dosing. Plaintiffs next allege that Defendants "failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly and inaccurately that one dosage fit all patients." Am. Compl. ¶ 82(t); *see also id*. ¶¶ 61, 66-69. The fact is, however, that Eliquis does not have "one size fits all" dosing. The FDA-approved Eliquis label includes a specific section on "Dosage Adjustments," with recommendations on dosing for patients who are older, leaner, and/or those who have impaired kidney function. *See* Ex. 4 (2012 Label), at 2. Specifically, the label recommends that the Eliquis dose be reduced by half (from 5 mg twice a day to 2.5 mg twice a day) in patients with atrial fibrillation who have two out of three of the following characteristics: age $\geq$ 80 years, body weight $\leq$ 60 kg, and serum creatinine $\geq$ 1.5 mg/dl. *See id*. Dosing reduction is also recommended in patients who are on certain medications that may affect Eliquis metabolism. *See id*. at 2-3.

Surgery and Lack of Warnings or Data. Plaintiffs also claim that the Eliquis label contains "no guidance from defendants on when to stop using Eliquis in advance of the surgery." Am. Compl. ¶ 70. Plaintiffs are again mistaken. The original FDA-approved label includes a

section devoted to "Discontinuation for Surgery and Other Interventions," which states:

> ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled.

Ex. 4 (2012 Label), at 3. It also explains that the half-life of Eliquis is "about 12 hours" and that "when the drug is stopped for surgery, anticoagulation persists for at least a day." *Id*. at 14.

Risk of Bleeding with Head Trauma. Plaintiffs further assert that patients who take Eliquis who experience "a head injury may suffer an unstoppable, and potentially fatal, internal bleeding event" and allege, without any reference, that with Eliquis, unlike with warfarin, "there is believed to be a greater risk of a bleeding event occurring in the head even after a CT-scan." Am. Compl. ¶¶ 73-74. Plaintiffs' claims on this topic are again at odds with the Eliquis labeling. First, as noted above, the Eliquis label clearly warns that Eliquis "can cause serious, potentially fatal bleeding," that "[t]here is no established way to reverse the anticoagulant effect of apixaban," and that "[a] specific antidote for ELIQUIS is not available." Ex. 4 (2012 Label), at 1, 5. This is true regardless of the cause of the bleeding. Second, as Plaintiffs themselves acknowledge, the FDA-approved Medication Guide, which is part of the Eliquis labeling, specifically advises patients to "Call your doctor or healthcare provider right away if you fall or injure yourself, especially if you hit your head. Your doctor or healthcare provider may need to check you." *Id*. at 29. Third, as reflected in the FDA-approved label, the ARISTOTLE trial showed that patients taking Eliquis were 59% less likely to experience a head bleed than those taking warfarin. *Id*. at 7. Finally, Plaintiffs' claims regarding head trauma bear no connection to this case, as Mr. Utts's alleged injury is a gastrointestinal bleed, not a head bleed.

Lack of a Reversal Agent. Plaintiffs' Amended Complaint also includes a series of new allegations about a reversal agent (AndexXa) that is currently in development by a company

(Portola) that is not a defendant in this litigation. *See* Am. Compl. ¶¶ 86-89. While Plaintiffs state that Defendants cooperated with Portola in developing the reversal agent and acknowledge that the agent was recently rejected by FDA, they make the somewhat bizarre claim that the Eliquis labeling is defective because "[n]o mention of this antidote is made." *Id*. ¶ 86. It is not clear what Plaintiffs expect Defendants to say in their labeling about an agent that has not been approved by FDA, particularly given that the labeling already prominently states that no reversal agent or antidote is available for Eliquis.

In sum, the Eliquis label "clearly and explicitly warned" Mr. Utts's physician about the specific adverse event allegedly suffered by Plaintiff (internal bleeding) and addressed the very issues Plaintiffs now claim made the labeling inadequate. *Dash*, 74 F.3d at 1245. While Plaintiffs' Amended Complaint includes eleven separate causes of action, the gravamen of each is that Defendants failed to adequately warn about the bleeding risk associated with Eliquis use and about the lack of a reversal agent. *See*, *e.g.*, Am. Compl. ¶¶ 94, 105, 126, 131, 159, 169, 183. Because the warnings in the Eliquis label are adequate as a matter of law, Plaintiffs' warnings claims, which underlie each and every one of Plaintiffs' causes of action, should be dismissed with prejudice.

III. Each Cause of Action in Plaintiffs' Amended Complaint Should Be Dismissed In Its Entirety for Independent Reasons.

In addition to the preemption of Plaintiffs' claims and the adequacy of the Eliquis label as a matter of law, each of which dispose of the Amended Complaint in its entirety, Plaintiffs' individual causes of action also fail for the additional reasons discussed below.

A. Plaintiffs Fail to State a Cause of Action for Manufacturing Defect.

In its December 23, 2016 Order, the Court stated that Plaintiffs' "complaint fails to identify or explain how the product ingested by Mr. Utts either deviated from the defendants' intended result/design or from other seemingly identical product models. A bare allegation that

the product had a manufacturing defect is too conclusory to plead a plausible claim or give the defendants fair notice." Order, at 36. On this basis, the Court dismissed the manufacturing defect claim, with leave to amend. Plaintiffs have now amended their Complaint, but still have not come forward with any allegations as to how the Eliquis pills Mr. Utts took deviated from the design approved by FDA. Accordingly, Plaintiffs' manufacturing defect claim (their 1st Cause of Action) should be dismissed with prejudice.

B. Plaintiffs' Strict Liability and Negligent Failure-to-Warn Claims Are Inadequately Pled.

Plaintiffs assert four causes of action premised on an alleged failure to warn about the bleeding risk associated with Eliquis use and the lack of a reversal agent: Failure to Warn (2nd Cause of Action), Product Liability - Strict Liability (3rd Cause of Action), Negligence and Gross Negligence (4th Cause of Action), and Negligence – Failure to Warn (5th Cause of Action).[12] *See* Am. Compl. ¶¶ 105, 112, 131, 147. As discussed above, all of Plaintiffs' warnings claims fail because they are preempted by federal law and because the warnings in the Eliquis label are adequate as a matter of law. Plaintiffs' claims also fail because the Amended Complaint does not provide sufficient facts for the Court to infer that "no warning was provided or the warning was inadequate" and "that the inadequacy or absence of the warning caused the plaintiff's injury." *See Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); *see also Plummer v. Lederle Labs.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law).

[12] To the extent Plaintiffs allege that Defendants failed to adequately test Eliquis, such claims fail because no independent duty to test exists under California law. *See Phillippi v. Stryker Corp.*, No. 2:08-CV-02445, 2010 WL 2650596, at *2 (E.D. Cal. July 1, 2010), *aff'd*, 471 F. App'x 663 (9th Cir. 2012) ("failure to test [a] product cannot, by itself, either cause injury or be a source of liability of the manufacturer."). Furthermore, Plaintiffs' allegations related to the design of Eliquis should be stricken pursuant to the Court's December 23, 2016 Order dismissing all design defect claims on preemption grounds. *See, e.g.*, Am. Compl. ¶ 109 ("The Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was ***defective in design and/or formulation***") (emphasis added).

Plaintiffs offer a laundry list of alleged problems with the Eliquis label, including, for example, failure to warn "about the true safety risks associated with the use of Eliquis," Am. Compl. ¶ 101(c); "that there is no drug, agent, or means to reverse the anticoagulation effects of Eliquis," *id*. ¶ 101(f); "the increased risk of gastrointestinal bleeds," *id*. ¶ 101(j); "the need to assess renal [and] hepatic functioning," *id*. ¶ 101(k, n); the need to "monitor [] patients closely for signs of neurological impairment," *id*. ¶ 101(l); and "the need for more comprehensive, more regular medical monitoring." *Id*. ¶ 101(t). Missing, however, are specific *facts* that would support an inference that these alleged labeling deficiencies caused the warnings in the Eliquis label to be inadequate and, perhaps more importantly, that changing the labeling (to the extent that Defendants could have done so independent of FDA) would have prevented Mr. Utts from suffering internal bleeding. For this reason also, Plaintiffs' strict liability and negligent failure-to-warn claims should be dismissed.[13]

C. Plaintiffs' Causes of Action for Breach of Warranty Are Inadequately Pled.

Plaintiffs have also failed to correct the pleading deficiencies that led the Court to dismiss their express and implied warranty claims. As the Court noted in its Order, Plaintiffs' original complaint only included vague allegations that were insufficient to support their warranty claims. *See* Order, at 38, n. 9. With regards to express warranty claims, the Court found that Plaintiffs "d[id] not identify the express warranties on which this claim relies, including whether they appeared in the labeling and package inserts for the drug, which were approved by the FDA, whether they appeared in an advertising campaign for the drug, or how the particular warranty was breached." *Id*. at 38. Likewise, with regards to the implied warranty claims, the Court noted

[13] To the extent Plaintiffs claim that Defendants "overpromoted" Eliquis in their direct to consumer advertising, *see* Am. Compl. ¶ 133(f), the only allegations supporting such claim appear to be references to three commercials in ¶¶ 43-44 of the Amended Complaint. Merits aside, those commercials did not air until "2015 and 2016," after Mr. Utts's alleged injury had already occurred. *Id*. ¶ 43. Accordingly, those commercials could not have had any impact on Mr. Utts's decision to take Eliquis.

that Plaintiffs only included broad fitness and merchantability claims that "appear to be challenging . . . the FDA's approval of Eliquis for sale to consumers." *Id*. at 39.

The allegations in the Amended Complaint do not materially differ from those in the original complaint. Plaintiffs' allegations are no less vague, claiming broadly that Defendants warranted that "Eliquis was safe and efficacious for its intended uses," "was not unreasonably dangerous," was "fit for its intended use," "had been fully and adequately tested for long-term use," was "safe to use in the treatment of atrial fibrillation," "was safe and of merchantable quality," and "was fit for use for the ordinary purposes." *See* Am. Compl. ¶¶ 164, 168, 182. Missing entirely is any detail as to "the contents of any specific warranty or breach thereof," where such warranty appeared, or how it was made. *Wendell v. Johnson & Johnson*, No. C 09-04124, 2010 WL 271423, at *5 (N.D. Cal. Jan. 20, 2010). Indeed, the only somewhat specific allegation relates to the adequacy of the warnings in the Eliquis labeling. *See* Am. Compl. ¶ 168 ("Defendants expressly represented . . . that the side effects [Eliquis] did produce were accurately reflected in the warnings"). Even if such claim was adequately pled (which it is not), it would be preempted for the reasons discussed above. Accordingly, Plaintiffs' warranty claims (6th and 7th Causes of Action) should be dismissed with prejudice.

D. Plaintiffs' Fraud Causes of Action Fail As a Matter of Law.

Pursuant to Fed. R. Civ. P. 9(b), allegations of fraud and misrepresentation must be pled with particularity, and must specifically include information about the nature, format, and content of the alleged representation or omission.[14] The purpose of these enhanced pleading requirements is to give a defendant fair notice of the claim against it, to protect a defendant's reputation from improvident charges of misconduct, and to limit strike suits. *See Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990). The Second Circuit has instructed that "these salutary

[14] A claim for negligent misrepresentation sounds in fraud and must be pled with particularity. *See Neilson v. Union Bank of Cal.*, 290 F. Supp. 2d 1101, 1141 (C.D. Cal. 2003).

purposes" are to be "rigorously enforce[d]." *Id.* Despite Plaintiffs' efforts to amend their pleadings, their fraud allegations still do not satisfy the heightened pleading standards of Rule 9(b), and fail for a number of additional reasons.

1. Fraud on the FDA Claims Are Preempted.

In its December 23, 2016 Order, this Court held that all fraud claims "premised on the interaction between the defendants and the FDA . . . are preempted and dismissed with prejudice." Order, at 42. Despite this ruling, Plaintiffs' Amended Complaint still contains numerous allegations related to alleged fraud on the FDA. *See* Am. Compl. ¶ 195 ("Defendants falsely and fraudulently represented to . . . the FDA"); ¶ 195 (a-c) ("All of this data was fraudulently submitted to the FDA"); ¶ 203 ("Defendants . . . withheld information from the FDA which they were required to report"); ¶ 223 ("Defendants breached their duty in representing Eliquis' serious side effects to . . . the FDA"). These fraud-on-the-FDA allegations should be stricken.

2. Plaintiffs' New Allegations Are Insufficient to Support a Cause of Action for Fraud / Fraudulent Concealment.

In their Amended Complaint, Plaintiffs identified for the first time several specific documents, which they contend contain fraudulent misrepresentations and omissions. *See* Am. Compl. ¶ 195. These include three pages from the Eliquis.com website, a Dosing Guideline from March 2014, a package insert from December 2012, and a package insert from March 2014. As discussed below, the statements Plaintiffs point to in these documents are insufficient to support a cause of action for fraud under the heightened pleading standards required by Rule 9(b).

Package Inserts from December 2012 and March 2014. Plaintiffs allege that the package inserts from December 2012 and March 2014 contained fraudulent representations and omissions regarding the dosing of Eliquis and the bleeding risk associated with the lack of a reversal agent. *See* Am. Compl. ¶¶ 195(e-f). These claims are nothing more than failure-to-warn allegations repackaged as fraud claims. Absent "newly acquired information," Defendants no

more could have independently changed the March 2014 label than they could have changed the original, FDA-approved label issued in December 2012. As discussed above, Plaintiffs have not identified any "newly acquired information" that could have supported a change to the dosing recommendations or the warnings about the bleeding risk with Eliquis pursuant to CBE regulations, nor identified any basis to support a claim that the representations in these labels were fraudulent in any way.[15] Accordingly, Plaintiffs' allegations about the 2012 and 2014 package inserts are preempted by federal law and should be stricken.

March 2014 "Dosing Guidelines". Plaintiffs allege that the March 2014 "Dosing Guidelines", which are provided to physicians (and are available on the Eliquis website) as a reference to help reinforce the dosing information included in the Eliquis label, "misled prescribing physicians and consumers to believe" that Eliquis was safe for use in patients with moderate or severe renal impairment and that no routine monitoring is necessary. *See* Am. Compl. ¶ 195(d). Plaintiffs base this claim on two statements in the guidelines: that "[n]o dose adjustment [is] required in patients with mild, moderate, or severe renal impairment" and that Eliquis "[d]oes not require routine monitoring using international normalized ratio[] (INR) or other tests of coagulation." *Id*. These statements, however, are entirely consistent with the FDA-approved Eliquis labeling. *See* Ex. 4 (2012 Label), at 17, Fig. 3 (stating that "no dose adjustment" is required for patients with mild, moderate, and severe renal impairment); *id*. at 13 (stating that INR and other coagulation tests are "not useful in monitoring the anticoagulation effect of apixaban"). Plaintiffs have not alleged any facts to suggest that those statements are incorrect, that Defendants knew those statements to be incorrect, or that Defendants acted fraudulently in any other way in issuing these guidelines.

[15] To the extent Plaintiffs base these claims on an allegation that Defendants withheld or misrepresented information to FDA concerning the conduct and results of ARISTOTLE, as the Court recognized, such allegations are preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Furthermore, because any documents that provide information about medication dosing are considered by FDA to be labeling, the information included in the guidelines must be consistent with the FDA-approved Eliquis label. *See* 21 C.F.R. § 201.100(d); *see also Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 394 (6th Cir. 2013). As Plaintiffs have not identified any data that would have supported any change to the FDA-approved dosing recommendations, Plaintiffs' claims based on the contents of the Dosing Guidelines are preempted.

Eliquis.com Website. Plaintiffs also claim that Defendants made three fraudulent representations on the Eliquis.com website: (1) that Eliquis was proven effective for nonvalvular atrial fibrillation in Phase III studies, *see* Am. Compl. ¶ 195(a), (2) that Eliquis is the only anticoagulant that demonstrated superiority in both stroke and systemic embolism and major bleeding versus warfarin, *see id*. ¶ 195(b), and (3) that Eliquis had less major bleeding than warfarin and did not require routine monitoring, *see id*. ¶ 195(c). Each of those representations is true and consistent with FDA's medical review and the FDA-approved label. *First*, Eliquis was approved by FDA as safe and effective for the treatment of nonvalvular atrial fibrillation, based on the results of its Phase III studies.[16] *See* Ex. 4 (2012 Label), at 2, 18-23. If FDA had not concluded that Eliquis was effective for this indication, it would not have approved the medication.[17] *Second*, FDA's pre-approval medical review concluded that Eliquis "was superior

[16] With regard to Plaintiffs' claims about ARISTOTLE, FDA carefully evaluated the conduct of the study and its results. *See* Ex. 8 (Apixaban Medical Reviews), at 3-5, 53-73, 119-20, 124-26, 180-86. FDA determined that concerns related to the design and conduct of the trial had been addressed by BMS and did not affect the overall outcomes of the study or FDA's conclusions about the safety and efficacy of Eliquis. *Id*. After completing its review, FDA approved for inclusion in the Eliquis label a summary of the results from ARISTOTLE, which Plaintiffs now describe as fraudulent. As noted earlier, any claims premised on alleged fraud on the FDA are preempted under *Buckman*, and any claims related to the original FDA-approved label are preempted as well.

[17] FDA only may approve a drug if it finds that the drug "is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof" and "will have the effect it purports or is represented to have." 21 U.S.C.A. § 355(d)(1-5).

to warfarin for the primary efficacy and safety endpoints as well as mortality" and approved a label that states that Eliquis "was superior to warfarin for the primary endpoint of reducing the risk of stroke and systemic embolism . . . [and] showed significantly fewer major bleeds than warfarin." Ex. 8 (Apixaban Medical Reviews), at 54; Ex. 4 (2012 Label), at 19. *Third*, while warfarin requires routine monitoring, FDA approved Eliquis without the need for monitoring.

In sum, as is the case with Plaintiffs' numerous vague fraud-based allegations (*see, e.g.*, Am. Compl. ¶¶ 201, 202, 206, 208, 217), none of the specific statements discussed above provide an adequate factual basis for Plaintiffs' fraud claims. Furthermore, Plaintiffs do not allege which, if any, of the statements were actually seen and relied on by Mr. Utts's physician at the time he prescribed Eliquis to Mr. Utts, as required under California law. *See Hawkins v. Medtronic*, No. 1:13-CV-00499, 2014 WL 346622, at *13 (E.D. Cal. Jan. 30, 2014) (dismissing fraud claims because plaintiff "fail[ed] to allege not only the content of the off-label promotion directed at his spine surgeon and on which the surgeon relied, but he also fail[ed] to allege who made those representations to his surgeon and when the representations were made"); *Mirkin v. Wasserman*, 858 P.2d 568, 572 (Cal. 1993) (rejecting "fraud-on-the-market" doctrine and holding that reliance is a required element of a fraud claim under California law). Accordingly, Plaintiffs' fraud / fraudulent concealment claims (8th Cause of Action) should be dismissed.

3. Plaintiffs' Allegations Are Insufficient to Support a Cause of Action for Negligent Misrepresentation.

In their Amended Complaint, Plaintiffs do nothing more than recite the elements of a claim for negligent misrepresentation. *See* Am. Compl. ¶¶ 215-227. Missing entirely is any detail as to the substance, nature, or circumstances of the alleged misrepresentations—the "who, what, and when" of the alleged conduct—as required pursuant to Rule 9(b). *Ressler v. Liz Claiborne, Inc.*, 75 F. Supp. 2d 43, 52 (E.D.N.Y. 1998), *aff'd sub nom. Fishbaum v. Liz Claiborne, Inc.*, 189 F.3d 460 (2d Cir. 1999). Accordingly, Plaintiffs' negligent

misrepresentation claims (9th Cause of Action) should also be dismissed.

E. Plaintiffs' Cause of Action for Violation of Consumer Protection Laws Is Inadequately Pled.

In support of their consumer protection claim, Plaintiffs allege only that Defendants "engaged in unfair, deceptive, false and fraudulent acts and practices in violation of California law" by "[p]ublishing instructions and product material containing inaccurate and incomplete factual information," "[m]isrepresenting the nature, quality, and characteristics about the product," and "[e]ngaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding." Am. Compl. ¶¶ 230, 231. Such "[t]hreadbare recital[] of the elements of a cause of action, supported by mere conclusory statements" is entirely insufficient to maintain a claim for violation of California consumer protection laws. *Wendell v. Johnson & Johnson*, 2010 WL 271423, at *2 (*quoting Aschroft*, 556 U.S. at 678). That is particularly true where, as here, the claims are premised on allegations of fraudulent conduct, which must be pled with particularity under Fed. R. Civ. P. 9(b). *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009); *In re Hydroxycut Mktg. & Sales Practices Litig.*, 801 F. Supp. 2d 993, 1005 (S.D. Cal. 2011). Absent from Plaintiffs' Amended Complaint are any specific allegations—pled with the particularity required under Rule 9(b)—that could provide a factual basis for their consumer protection claims. Accordingly, those claims (10th Cause of Action) should be dismissed.

F. Plaintiff Ciara Utts's Loss of Consortium Claim Is Derivative.

Under California law, an action for loss of consortium is derivative and "is, by its nature, dependent on the existence of a cause of action for tortious injury to a spouse." *LeFiell Mfg. Co. v. Super. Ct.*, 282 P.3d 1242, 1246 (Cal. 2012). Because all other counts fail as a matter of law, Mrs. Utts's loss of consortium claim (11th Cause of Action) also must be dismissed.

IV. Plaintiffs' Demand for Punitive Damages Should Be Denied.

Punitive damages are only recoverable where "it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294; *see also Taylor v. Super. Ct.*, 598 P.2d 854, 862 (Cal. 1979) (holding that "punitive damage is recoverable only for malicious or other intentional injury"). Punitive damages are an "extraordinary" remedy, *see Dyna-Med, Inc. v. Fair Emp't & Hous. Comm'n*, 743 P.2d 1323, 1328 (Cal. 1987), and are only allowed in the "clearest of cases." *Woolstrum v. Mailloux*, 190 Cal. Rptr. 729, 734 (Cal. App. Dep't Super. Ct. 1983). To support an award of punitive damages, the conduct must be of "such severity or shocking character [as] warrants the same treatment as accorded to willful misconduct—conduct in which defendant *intends* to cause harm." *Id*. at 735. Here, Plaintiffs do not allege—with the particularity required under Rule 9(b)—that Defendants acted with malice or committed fraud such that an inference of intent to harm can be drawn. Accordingly, Plaintiffs' demand for punitive damages should be denied.

CONCLUSION

For the reasons stated above, and pursuant to Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 9(b), Plaintiffs' Amended Complaint should be dismissed in its entirety.

Dated: New York, New York.
February 3, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Loren H. Brown, hereby certify that on February 3, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Loren H. Brown